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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
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3733

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08/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/695,067 | YOUNG ET AL. |
| | Examiner | Art Unit |
| | Jerry Cumberledge | 3733 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 May 2007.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-61 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-61 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 28 October 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.
 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____.
 5) Notice of Informal Patent Application
 6) Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6, 10-15 and 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "the first rod connecting portion" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 10, line 1 recites "...the shaft is slidably received..." Appropriate correction is required.

Claim 22, line 1 recites "...the shaft is slidably received..." Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 16-23, 29-34, 43-53, 60 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Korhonen et al. (US Pat. 5,669,910).

Korhonen et al. disclose a cross-connector assembly for interconnecting a pair of orthopedic rods (Fig. 4, below), said assembly comprising: an interconnection element including a first body and a stud, said first body having a first aperture formed therein and said stud extending from the body; a first rod connector including a first shaft terminating in a first rod engaging portion and a projection extending laterally from said first shaft and displaced axially along said first shaft from the spinal rod engaging portion, said first shaft and said projection slideably received within the first aperture; a second rod connector including a second shaft having a second body carried thereon, said second body having a second aperture formed therein, said second aperture having the stud received therein; and a fastener configured to engage with the stud (Fig. 2, ref. 34). The first aperture defines a first axis (Fig. 4, the axis that extends from near bottom ref. 46 to near top ref. 46, along the rectangular portion of the aperture) extending through the first body and the stud is positioned to lie substantially orthogonal to the axis (Fig. 4, below). The first aperture is non-circular, since it has a rectangular component (Fig. 4, near bottom ref. 46 to near top ref. 46). The first shaft exhibits a substantially round cross-sectional profile (Fig. 4). The first rod connecting portion comprises a curved member configured to at least partially encircle a spinal rod, since the rod engaging portion has curves near ref. 20 and ref. 23, which can be used to encircle a spinal rod. The first rod connecting portion comprises a threaded aperture (Fig. 4, ref. 23) extending into the curved member. The first shaft is substantially straight (Fig. 4). The first shaft is curved so as to be non-linear, since it has rounded edges. The second shaft is curved, since it has rounded edges. The first shaft is slidable received

within the first aperture to allow the first rod engaging portion to be spaced from the second rod engaging portion at varying distances. The second shaft is rotatable about an axis formed by the stud to vary an angle defined by the first shaft and the second shaft. The first shaft and the second shaft are curved, since they have rounded edges. The second aperture of the second shaft is configured to allow the second shaft to pivot along the axis defined by the stud. The first rod connector is rotatable about an axis defined by the first shaft. The second body on the second shaft includes a lower surface (Fig 4, surface near ref. 38), wherein engagement of the fastener to the stud urges the lower surface to contact the first shaft and clamp the fast shaft in a first orientation relative to the second shaft. The first rod connector is rotatable about an axis defined by the first shaft. Rotation of the first rod connector induces the projection to contact said first body and inhibit removal of the first shaft from the first aperture. The first rod connector is rotatable about an axis defined by the stud. The second rod connector is rotatable about an axis defined by the stud. The first shaft of the first rod connector and the second shaft of the second rod connector are curved, since they have rounded edges. The first shaft is slidable received within the first aperture to allow the first rod engaging portion to be spaced from the second rod engaging portion at varying distances. The assembly further comprises a first spinal rod (Fig. 1, ref. 12) secured to the first rod engaging portion (Fig. 1) and a second spinal rod (Fig. 1, ref. 14) secured to the second rod engaging portion, wherein the first spinal rod is positioned to lie non-parallel to the second spinal rod. Engagement of the fastener to the stud secures the second rod connector in a selected orientation. The first spinal rod defines a first plane

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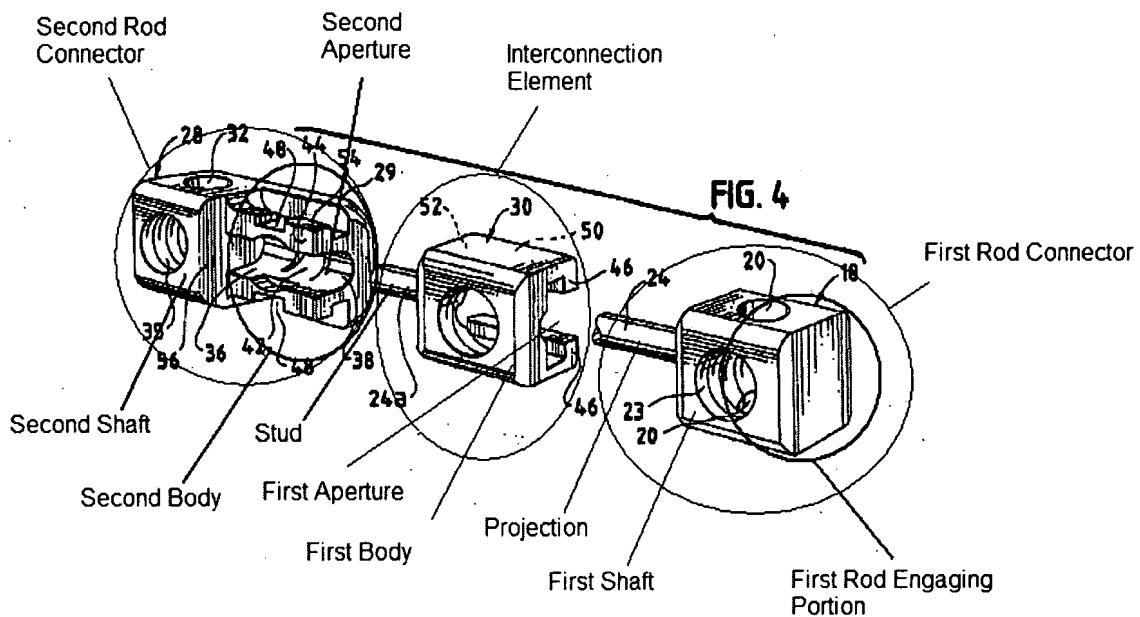
and the second spinal rod is positioned to lie in a plane different from the first plane.

The first rod engaging portion comprises a hook sized to at least partially encircle a spinal rod, said hook extending laterally from the first shaft in a first direction and wherein said projection extends laterally from the first shaft along said first direction.

The definition of hook, according to the Merriam-Webster Online Dictionary, is "a curved or bent device for catching, holding or pulling." The rod engaging portion can be considered to be a hook, because it has curves (around the circular bores), and it is used for holding the rod. It is extending laterally from the shaft, since it is coming from the side of the shaft (Fig. 4). The projection defines a finger, lobe, or ridge. The projection can be considered to be a finger. At least one of the first shaft or the second shaft has a smooth exterior surface (Fig. 4) and a round or oval cross-sectional profile (Fig. 4). The first and second shafts are configured to nest with each other (Fig. 2). The stud has a longitudinal axis, and the first shaft has a longitudinal axis, and the longitudinal axis of the stud is oblique to the first shaft longitudinal axis. With regard to the longitudinal axes, the axes need not be in the center of the respective parts but can be offset from the center and can drawn at an angle to each other. The first shaft and the second shaft are capable of pivoting with respect to each other between a first position in which said first shaft and said second shaft are substantially parallel and a second position in which said first shaft and said second shaft define an interior angle between them that is less than 180 degrees.

Korhonen et al. disclose a method of treating a spinal defect, said method comprising: securing a first spinal rod and a second spinal rod each to two or more

vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim 1 (column 3, lines 16-22).

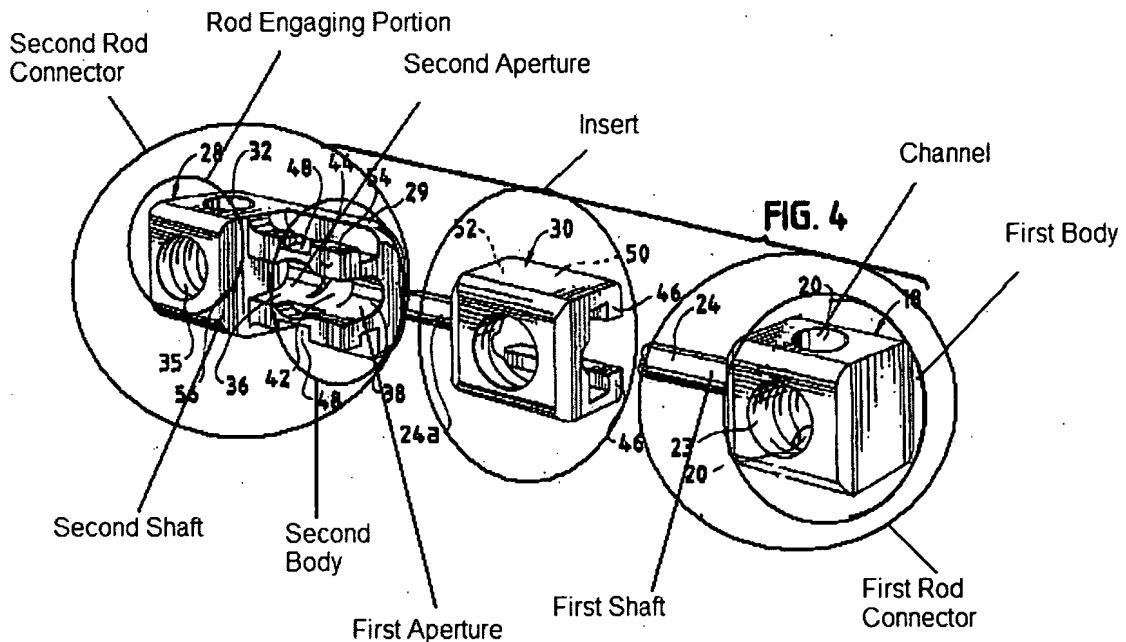


Korhonen et al. disclose a cross-connector assembly (Fig. 4, below) for interconnecting a pair of orthopedic rods, said assembly comprising: a first rod connector including a first shaft terminating in a first body having a channel therethrough a second rod connector including a second shaft defining a longitudinal axis and terminating on a first end with a rod engaging portion and on an opposite second end with a second body, said second body having a first aperture therein defining a first central axis positioned to lie in a plane with the longitudinal axis, said second rod connector also including a second aperture therein defining a second central axis positioned to lie at an angle to the first central axis; an insert configured to

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engage the first shaft of the first rod connecting member extending through the first aperture and positioned in said second body and in communication with said second aperture; and a fastener (Fig. 2, ref. 41) extending through the second aperture of the second body and engaging one or more of the insert (Fig. 2, ref. 41), the second body of the second rod connector, or the first shaft of the first rod to secure the orientation of the first rod connector relative to the second rod connector. The first shaft of the first connector is straight (Fig. 4). The first shaft of the first connector is curved, since it has rounded edges (Fig. 4). The first aperture and the second aperture intersect (Fig. 4). The fastener engages with both the insert and the first shaft. The fastener engages the insert thereby securing the first rod connecting member in a desired orientation relative to the second rod connecting member. The fastener engages the first shaft thereby securing the first rod connecting member in a desired orientation relative to the second rod connecting member. The fastener engages the second body of the second rod connector thereby securing the first rod connecting member in a desired orientation relative to the second rod connecting member.

Korhonen et al. disclose a method of treating a spinal defect, said method comprising: securing a first spinal rod and a second spinal rod each to two or more vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim 44 (column 3, lines 16-22).

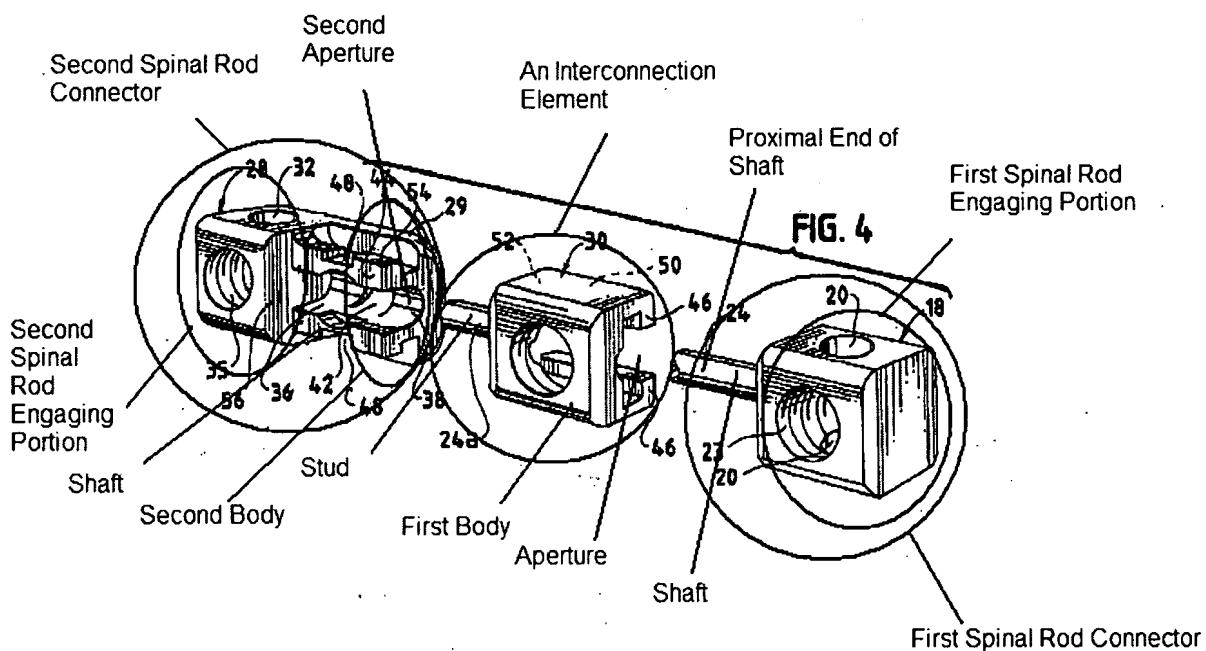


Korhonen et al. disclose an cross connector (Fig. 4, below) comprising an interconnection element including a first body having an aperture formed therein and a stud extending from said body; a first spinal rod connector including a first shaft having a proximal end received within said aperture and a distal end carrying a first spinal rod engaging portion configured to at least partially encircle a spinal rod; a second spinal rod connector having a second body on a proximal end, a second spinal rod engaging portion on a distal end and a second shaft extending therebetween , wherein said body includes a second aperture having the stud received therein; and a single fastener (Fig. 2, ref. 41) to secure the first and second spinal rod connectors to each other at a user defined orientation relative to each other.

Korhonen et al. disclose a method of treating a spinal defect, said method comprising: securing a first spinal rod and a second spinal rod each to two or more

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vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim 53 (column 3, lines 16-22).



With regard to the statements of intended use and other functional statements (e.g. ...the first shaft is slidably received within the first aperture..., ..., the second shaft is rotatable about an axis formed by the stud..., ...configured to allow the second shaft to pivot..., ...rotation of the first rod connector induces the projection to contact said first body..., ...said first shaft and said second shaft are capable of pivoting with respect to each other...etc.), they do not impose any structural limitations on the claims distinguishable over the device of Korhonen et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not

require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Korhonen et al.* (US Pat. 5,669,910).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the stud being monolithic with the body, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Claims 35, 36, 39-42, 54, 55 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korhonen et al. (US Pat. 5,669,910) in view of Schluzas (US Pat. 6,554,832 B2).

Korhonen et al. disclose the claimed invention, except for an insert, and the insert and the first aperture defining a ball and socket joint.

Schluzas discloses a cross-connector assembly with an insert (Fig. 2, ref 48) and a first aperture (Fig. 2, near ref. 50), and the insert and the first aperture forming a ball and socket joint (Fig. 4), in order to allow the connecting rod to pivot (column 2, lines 36-39) and conform to the specific area of the spine that is being stabilized (Fig. 1). The insert is configured to at least partially encircle the first shaft (Fig. 2, ref. 52 and 42). The insert is configured to at least partially encircle the stud, since the stud and the first shaft have approximately same diameter (Korhonen et al., Fig. 2). The insert can be placed in the second aperture to define a ball and socket joint, similar to the ball and socket joint of the first aperture. The insert is substantially spherical on one end (Fig. 2, ref 50) and substantially cylindrical on the other end (Fig. 2, the end near ref. 40). The insert in combination with the first body can restrict movement of the first shaft to inhibit disassembly of the apparatus. The insert can be positioned within the second body and is configured to at least partially encircle the second shaft. The insert allows the connecting rod to pivot and to conform to the specific area of the spine that is being stabilized (Fig. 1).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the cross-connector assembly of Korhonen

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et al. with the insert (Fig. 2, ref. 48) and first aperture (Fig. 2, near ref. 50) of Schluzas, and the insert and the first aperture forming a ball and socket joint (Fig. 4) of Schluzas, in order to allow the connecting rod to pivot (column 2, lines 36-39) and conform to the specific area of the spine that is being stabilized (Fig. 1).

Claims 13-15, 24-28, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korhonen et al. (US Pat. 5,669,910) in view of Sherman et al. (US Pat. 5,976,135).

Korhonen et al. disclose the claimed invention except for the washer and the washer having splines and the second spinal rod connector having a lower surface, which has a second set of splines.

Sherman et al. disclose a lateral connector assembly comprising a washer (Fig. 7, ref. 55) and the washer having splines (Fig. 7, ref. 60) and recesses (Fig. 6, ref. 58) and the second spinal rod connector having a lower surface (Fig. 11, ref. 72), which has a second set of splines (Fig. 11, ref. 82) which can matingly engage the splines of the washer, which allow the lateral connector to assume variable angular positions with respect to the washer (column 7, lines 1-19). The washer is made from a deformable material, since any material will deform when pressure is applied to it. The washer is capable of deforming when the fastener engages the stud. Engagement of the fastener can frictionally engage the washer to the first shaft of the first rod connector. The washer is capable of being carried by the stud and positioned between the stud and the second aperture of the second rod connecting member. This set-up enables the lateral

connector to assume variable angular positions with respect to the washer (column 7, lines 1-19).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the cross-connector assembly of Korhonen et al. with the a washer and the washer having splines and the second spinal rod connector with a lower surface, which has a second set of splines of Sherman et al., in order to allow the lateral connector to assume variable angular positions with respect to the washer (column 7, lines 1-19).

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Korhonen et al. (US Pat. 5,669,910) in view of Burgess et al. (US Pub. 2003/0114853 A1).

Korhonen et al. disclose the claimed invention except for the first shaft comprising a protuberance extending laterally therefrom, said protuberance sized to be received within said first aperture.

Burgess et al. disclose a cross connector (Fig. 3, refs. 20 and 16) with a shaft (Fig. 3, ref. 14) comprising a protuberance (Fig. 3, ref. 28) extending laterally therefrom (best seen in Figs. 2 and 4), the protuberance being sized to be received with an aperture (Fig. 3, ref. 30), the protuberance and it corresponding mating surface allow for movement in three degrees of freedom over one another (paragraph 0008, lines 5-7).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the first shaft of Korhonen et al. with a

protuberance extending laterally therefrom as taught by Burgess et al., in order to allow the first shaft and the aperture in which it is found to move in three degrees of freedom relative to each other (paragraph 0008, lines 5-7).

Response to Arguments

Applicant's arguments filed 05/21/2007 have been fully considered but they are not persuasive.

With regard to Applicant's argument that Korhonen does not disclose a shaft and rod connector component, the Examiner respectfully disagrees. As stated in the previous Action, the Examiner found the argument that treating ref. 18 as both a first shaft and the first rod connector was persuasive, as the same reference should not be treated as two separate elements. However, claim 1 reads "...a first rod connector *including* a first shaft..." (emphasis added). Thus, the first shaft is a part of the first rod connector. The Korhonen reference discloses elements that can be considered to be a "first shaft" and a "first rod connector", where the first shaft is part of the first rod connector. These components are labeled in the remarked Fig. 4 above.

With regard to Applicant's argument that Korhonen does not show a stud as part of an interconnection element, the Examiner respectfully disagrees. Ref. 24 can be considered to be a projection, since it is projecting from ref. 18, while the ref. 24a (i.e. the left most portion of ref. 24) can be considered to be a stud. The definition of stud according to The American Heritage Dictionary of the English Language: Fourth Edition is "any of various protruding pins or pegs in machinery, used mainly as a support or

pivot." Since the leftmost end of ref. 24 is a pin that protrudes from the main body of ref. 24 (i.e. the rightmost portion of ref. 24), then ref. 24a can be considered to be a stud. Furthermore, the stud is associated with the interconnection element (remarked Fig. 4 above) and is shown extending from it (Fig. 4). Furthermore, as the claims stand there is no limitation requiring that the stud is structurally different from the projection (i.e. is not attached directly to, is wider than, etc.), thus ref. 24a can be considered to be a stud, while ref. 24 can be considered to be a projection.

With regard to Applicant's argument that the first shaft and the first projection are not slidably received in the first aperture, it is noted that this statement of intended use and other functional statements do not impose any structural limitations on the claims distinguishable over the device of Korhonen, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Specifically, the first shaft and the first projection are capable of being placed into the first aperture, at least in part. The first projection is clearly capable of being placed (or slid) into the first aperture (Fig. 4 above). A corner of the first shaft can be placed (or slid) into the first aperture. Thus, the device of Korhonen is capable

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of this function. With regard to Applicant's argument regarding claim 11, the second shaft is capable of being rotated about an axis defined by the stud to vary an angle defined by the first shaft and the second shaft. This claim does not require that the second shaft rotate about the stud, but about an axis defined by the stud. Since an axis can extend further than the end portion of the stud itself, the second shaft must only be capable of rotating about an axis that extends from the end of the stud, in order to change the angle between the second shaft and the first shaft. This can be accomplished by aligning the second shaft with the axis of the stud (but not connecting the stud and the second shaft) followed by angling the second shaft with respect to the first shaft, while keeping at least a portion of the device along the axis of the stud.

Therefore, the device of Korhonen is capable of this function.

Due to a typographical error, claims 13-15 (claims regarding a washer) were rejected under 35 U.S.C. 102(b). This was clearly only a typographical error on the Examiner's part, as the rejection over Korhonen et al. in view of Sherman et al. addresses the fact that the Korhonen reference does not disclose a washer (Office Action, page 11, "Korhonen et al. disclose the claimed invention except for the washer and the washer having splines and the second spinal rod connector having a lower surface, which has a second set of splines"). Furthermore, Applicant acknowledges that the Korhonen reference does not disclose a washer (remarks, page 14, "As to the combination of Korhonen and Sherman, it is agreed that Korhonen does not show a washer.") Thus, in the previous Office Action it is clear that claims 13-15 should stand

rejected under 103(a) as being unpatentable over Korhonen et al. in view of Sherman et al., and this is reflected above in the rejections of these claims.

With regard to Applicant's argument that Korhonen cannot be combined with Schluzas, Sherman or Burgess, the Examiner respectfully disagrees. The test for obviousness is not whether the features of one reference may be bodily incorporated into the other to produce the claimed subject matter but simply what the combination of references makes obvious to one of ordinary skill in the pertinent art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571)

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272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC

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